IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

QT, INC., an Illinois corporation,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	No. 05 C 6387
	)	
MAYO CLINIC JACKSONVILLE, MAYO CLINIC ROCHESTER, MAYO FOUNDATION, MAYO CLINIC COLLEGE OF MEDICINE, and ROBERT L. BRATTON, M.D., individually,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff QT, Inc. brought this action against defendants Mayo Clinic Jacksonville, Mayo Clinic Rochester, Mayo Foundation, Mayo Clinic College of Medicine, and Robert L. Bratton, M.D., for injunctive relief and damages arising from alleged commercial disparagement, common law fraud, tortious interference with prospective economic advantage, negligence, negligent misrepresentation, violations of the Uniform Deceptive Trade Practices Act, and violations of the Consumer Fraud and Deceptive Business Practices Act. The allegations arise from two clinical trials conducted by Mayo Clinic Jacksonville and Bratton to evaluate the efficacy of the plaintiff's Q-Ray® Ionized Bracelet®. Plaintiff claims that defendants grossly mismanaged the studies and published and disseminated false and misleading statements concerning the studies' results. During the course of discovery plaintiff requested the participant forms from the first and second studies. Defendants agreed to produce the forms, but only with redaction of the identifying information of the participants

and any participant witnesses. In an effort to secure the personal identification information of the participants of both studies, plaintiff filed this motion to compel discovery of the unredacted informed consent and participant forms. For the reasons stated below, we deny in part plaintiff's motion to compel.

BACKGROUND

Plaintiff, the distributor of Q-Ray® Ionized Bracelets®, agreed to furnish Mayo Clinic Jacksonville and Bratton with its product so that defendants could test the efficacy of the bracelets on the reduction of muscle and joint pain. The parties entered into a contract in September 1999, defining the study to include 610 subjects to begin in October 1999 and conclude in November 1999. According to plaintiff, in or about April 2000, after 540 subjects had enrolled and begun participation in the trial, Mayo Clinic Jacksonville suspended and then terminated the study. Plaintiff alleges that Mayo Clinic Jacksonville and Bratton, the principal investigator in the trial, failed to follow various federal and clinic guidelines, including informed consent regulations. After the incomplete conclusion of the first trial, Mayo Clinic Jacksonville and Bratton undertook a second study. Plaintiff alleges that the second study was also replete with errors and mismanagement of the study design, protocol, recruitment, informed consent, statistical analysis, and administration.

Based on the results of the second study, Bratton prepared a written report, which was published and distributed in November 2002, in *Mayo Clinic Proceedings*. Accompanying the article, defendants executed a press release summarizing the conclusions. Neither the article nor the summary advocated the effectiveness of the Q-Ray® Ionized Bracelet®, finding that "[t]he results of this study suggest that the use of ionized bracelets for treating muscle and joint pain was no more effective for relieving muscoskeletal pain than was the use of placebo

bracelets" (cplt., ex. A, p.3). Based on its allegations that the first and second studies were replete with error, plaintiff brought this suit, alleging commercial disparagement, common law fraud, tortious interference with prospective economic advantage, negligence, negligent misrepresentation, and violations of the Uniform Deceptive Trade Practices Act and the Consumer Fraud and Deceptive Business Practices Act.

As part of the studies, Bratton had study participants read and sign an informed consent form.[1] The four-page consent form explains the purpose, length, and participation of the study, along with the risks, benefits, and costs of taking part in the study. The consent form also includes a note about confidentiality, stating that the data from the study would be published, but the participant's name and other identifying information would not be sent outside of Mayo Clinic "without permission unless the law allows it." The consent form required signatures of the participant, the individual obtaining consent, and a witness to the consent. A notation on the top of the consent form indicates that the form would be retained in the participant's medical record. Included with the consent form is a ten-page document we refer to as the patient eligibility and pain assessment form. Designating the participant (called the "patient") on the first page by name, clinic number, and date of birth, the patient eligibility portion of the form includes a series of five medical yes/no questions, three demographic questions, and three questions regarding the participant's knowledge and beliefs about the ionized bracelets. The pain assessment portion of the form includes an initial assessment about current joint or muscle pain and any serious injury associated with that pain. The rest of the pain assessment includes notations of the participant's pain throughout

[1]Because we only have access to the forms used in the second study, we base our analysis on those forms. We assume that the forms from the first study were similar, if not identical.

the study, designating pain levels from zero to ten for each affected part of the body. For the sake of convenience, we will refer to the informed consent, patient eligibility and pain assessment forms, together, as the clinical study participant questionnaire.

During the course of discovery plaintiff requested the clinical study participant questionnaires. Defendants agreed to produce the forms with redaction of the participant's name and identifying information, and the name of the witness if he or she was also a participant. Claiming that the names and identifying information of the participants in both studies is essential to developing its case, plaintiff brought this motion to compel the production of unredacted clinical study participant questionnaires. Defendants oppose the motion, claiming that the health information is privileged under both Florida and Illinois law.

DISCUSSION

Plaintiff asserts that the identity of the study participants is essential to making its case. Specifically, plaintiff claims that disclosure is necessary in order to determine which participants were also Mayo employees, and thus potentially biased or disqualified, and whether participants in the second study were improperly influenced by the first study. Plaintiff contends that the clinical study participant questionnaire does not fall within the protections of either federal or state law because it does not implicate privacy concerns and the study records at issue do not contain medical information. Further, plaintiff asserts that because the study participants are potential fact witnesses, their identities are discoverable. Not surprisingly, defendants disagree on all of the above claims. Specifically, defendants argue that state law is more protective than federal law regarding privacy of medical information, and that the state law protects medical information such as that contained in the clinical study participant questionnaires.

Although state substantive law controls in a diversity case (Armour Int'l Co. v. Worldwide Cosmetics, Inc., 689 F.2d 134, 135 (7th Cir.1982)), the parties are unwilling to agree as to whether Florida or Illinois law controls. Because the parties have not sufficiently briefed their choice-of-law arguments, and because we believe that the Illinois and Florida courts would agree to the outcome of this issue, we need not determine which law controls at this stage.

Plaintiff makes arguments under both federal law – pointing to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") – and state statutory and common law. Defendants's response asserts that HIPAA does not control because HIPAA expressly yields to state laws that give greater protection to patients' health information. We agree (*see* HIPAA, P.L. 104-191, § 264(c)(2); Northwestern Mem'l Hosp. v. Ashcroft, 362 F.3d 923, 924 (7th Cir. 2004)), and therefore focus on state law.[2]

Florida statute section 456.057 provides for confidentiality of medical records. Specifically, it states that "such records may not be furnished to, and the medical condition of a patient may not be discussed with, any person other than the patient or the patient's legal representative or other health care practitioners and providers involved in the care or treatment of the patient, except upon written authorization of the patient." F.S.A. § 456.067 (2005)[3]. Section 456.067 and its predecessors have been read to provide for a "broad physician-patient privilege of confidentiality for a patient's medical information...." Acosta v. Richter, 671 So.2d 149, 150 (1996). The purpose of the law is to "protect [] the patient's

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[2]The substantive provisions of Florida confidentiality law is more stringent than HIPAA. Lemieux v. Tandem Health Care of Florida, Inc., 862 So.2d 745, 748, n1 (Fla.Dist.Ct.App.2003). The same is true in Illinois. Moss v. Amira, 826 N.E.2d 1001, 1010-11 (Ill.App.Ct.2005) (Quinn, J., specially concurring).

[3]Section 456.057 provides four exceptions for when otherwise privileged information may be disclosed, none of which apply in this case.

interest in keeping the details and nature of his medical treatment confidential without fear of later disclosure by the one in whom he has placed his trust." Estate of Stephen ex rel. Clark v. Galen Health Care Inc., 911 So.2d 277, 280 (Fla. Dist. Ct. App. 2005).

Illinois law also guarantees privacy and confidentiality for patient medical records. The statute holds that "[n]o physician or surgeon shall be permitted to disclose any information he or she may have acquired in attending any patient in a professional character, necessary to enable him or her professionally to serve the patient." 735 ILCS 5/8-802.[4] The Illinois courts define a "physician-patient" relationship as "a consensual relationship in which the patient knowingly seeks the physician's assistance and in which the physician knowingly accepts the person as a patient." Bovara v. St. Francis Hosp., 700 N.E.2d 143, 146 (Ill. App. Ct. 1998).

There is a general reluctance in Florida and Illinois courts to disclose non-party medical records. *See* In re Fink, 876 F.2d 84, 85 (11th Cir.1989); Statman v. Lipman, 641 So.2d 453, 454 (Fla. Dist. Ct. App. 1994); Ekstrom v. Temple, 553 N.E.2d 424, 430 (Ill. App. Ct. 1990). The issue in contention, however, is whether the clinical study participant questionnaire actually falls into the category of privileged medical records; whether the forms fall within the ambit of the Florida or Illinois confidentiality statutes. We find that, when viewed in their entirety, they do.

Initially, we must determine whether the study participants were "patients" within the meaning of the statute. We first note that the study identified participants as "patients." While the informed consent form does identify the participant as "participant," the pain

[4]Section 8-802 also provides for eleven exceptions for when otherwise privileged information may be disclosed. None of the Illinois exceptions apply in this case.

assessment forms designate the participant as a "patient" in several different places (*see* plf's mem., ex. B). While this is certainly not dispositive, it does set the tone for the relationship between the participant and the investigator.

The participant's designation as "patient" is not the only cue to the participant that his or her relationship with the investigator is a professional medical relationship. Plaintiff admits that Mayo Clinic Jacksonville is part of a group of health care providers that provides health care services to patients (cplt., ¶ 6). In fact, Mayo Clinic is well-known as a premier health care and diagnostic facility. Therefore, as compared to an identical hypothetical study run at and through QT's corporate offices, those participating in studies run at and through the Mayo Clinic arguably anticipate a medical relationship with the investigators. *See* Chilly v. Knoll Pharmaceuticals, 295 N.J. Super. 478, 482, n3 (N.J. Super. Ct. App. Div. 1996) (in a clinical drug trial, although the participants were not patients of the drug company, they were patients of the doctor investigators.)

Participants also had a reasonable expectation of privacy in the study. The informed consent form indicated that the participants' names and other identifying information would be kept confidential, if possible. *Cf.* West v. Branham, 576 So.2d 381, 384 (Fla. Dist. Ct. App. 1991) (a party undergoing a medical examination performed at the request of an opposing party in litigation, for the sole purpose of obtaining evidence, is not a "patient" under the confidentiality statute). Because the purpose of the statute is to protect a patient's confidentiality where he has placed his trust in a health care professional, we believe that the patient's expectation of privacy is relevant and important. Because courts have generally refrained from defining whether clinical trial participants are "patients" for the purpose of confidentiality statutes, we look to the way the courts have construed the confidentiality

statutes with respect to others who have claimed its protections. For example, in Slim-Fast Foods Co. v. Brockmeyer, 627 So.2d 104 (Fla. Dist. Ct. App. 1993), the court found that the identities of consumers who filed complaints with the manufacturer of a nonprescription diet aid, in which they disclosed information about their medical conditions, was discoverable and not protected by Florida's privacy laws. The Slim-Fast court focused on the fact that those writing the letters neither asked for nor were given reason to believe that their letters would be kept confidential. Additionally, the court in Slim-Fast noted that, unlike other cases where confidentiality had been protected, those writing the letters forwarded them to a manufacturer, not to a doctor. This case is distinguishable on both points. First, the participants in the ionized bracelet study were guaranteed some privacy.[5] Second, the participants gave their medical information to a doctor conducting a study on a product that was marketed to have medical benefits. Thus, we find that the participants entered the study with a reasonable expectation of privacy. Based on the use of the term "patient" during the studies, the participants' expectations, the investigator's position as a medical doctor, and the bracelets' intended use for medical benefits, we find that the participants were "patients" under the confidentiality statutes.

Plaintiff argues that even if the participants were "patients," the clinical study participant questionnaire is not a medical record within the meaning of the confidentiality laws. Specifically, plaintiff argues that because the trial team was not providing health care services to the study participants as part of the study, any information gathered during the study cannot be defined as medical records for purposes of confidentiality. In thinking about

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[5]Although the informed consent included a caveat that the participants' names would be released if required by law, the underlying message of the confidentiality notation was that the Clinic would protect the participants' personal information as far as the law would allow.

the purposes behind the confidentiality laws, we cannot agree with plaintiff.

Neither Florida nor Illinois courts have explicitly defined whether records made in connection with a health-based clinical trial are "medical records."[6] Plaintiff argues that the clinical study participant questionnaire is analogous to sign-in logs found to be discoverable in Big Sun Healthcare Systems, Inc. v. Prescott, 582 So.2d 756 (Fla. Dist. Ct. App. 1991). In Big Sun Healthcare Systems, the Florida court held that an emergency room patient sign-in log was discoverable, including the patients' names. Plaintiff argues that, like the sign-in logs, the clinical study participant questionnaires do not contain information about medical problems, and therefore do not implicate patient privacy. We disagree. The sign-in logs in Big Sun Healthcare Systems included only the patient's name, whether the visit was initial or recheck, whether the patient belonged to certain specific care plans, and triage time. In contrast, the clinical study participant questionnaire contains the participant's name, address, telephone number, date of birth, background medical questions, demographic information, and pain assessment specific to parts of the body. The background medical questions ask whether the participant is pregnant and/or implanted with an internal electrical device, such as a pacemaker. The pain assessment portion asks the participant to note muscle and/or joint pain with respect to specific parts of the body, and to disclose whether he or she has had any major surgery on that area. While the four-page consent form is more like the sign-in logs in Big Sun Healthcare Systems, the patient eligibility and pain assessment forms are more like the triage reports withheld by the court in Big Sun Healthcare Systems. Like the patient

[6]We do note, however, that in In re Rezulin Products Liability Litigation, the courts held that medical records of patients who participated in clinical trials of a prescription diabetes medication was discoverable, but the names and identifying information must be redacted. 2002 WL 418028 (S.D.N.Y.2002); 178 F.Supp.2d 412 (S.D.N.Y.2001).

eligibility and pain assessment forms, the triage records included symptoms and past medical history, and were a part of a patient's medical chart. Additionally, as is true with the patient eligibility and pain assessment forms, but not true with the patient sign-in logs, the triage records were kept in a private area not accessible to other patients or participants. Thus, we find that the consent forms are not medical records, but the participant questionnaire and pain assessment forms are.

Finally, plaintiff argues that if the clinical study participant questionnaire is a medical record, the identity of the participants is still discoverable because the participants are potential fact witnesses. Plaintiff points to North Broward Hosp. Dist. v. Lucas, 448 So.2d 622 (Fla. Dist. Ct. App. 1984), to argue that "Florida law allows for disclosure of the identities of persons who could potentially be witnesses to the facts alleged in plaintiff's complaint" (plf's mem. at 15). The court in North Broward indicated that the plaintiff could discover the names of those present in a labor room who may have been potential witnesses in a medical malpractice action. Other Florida courts have also held that such fact witnesses are discoverable, but only where the plaintiff is seeking potential fact witnesses, not where the plaintiff seeks the name of a potential fact witness and medical information regarding that potential witness. *See* In re Fink, 876 F.2d at 85. Because the patient eligibility and pain assessment forms are medical records, plaintiff cannot access those medical records by claiming that each of the study participants is a potential fact witness.

We conclude, therefore, that the clinical study participant questionnaire, as a whole, is not discoverable without the redaction of the patient's identifying information. Although the information may be relevant in making the plaintiff's case, plaintiff's need does not outweigh the right of privacy and confidentiality of the non-party patients. *See* Community

Psychiatric Centers of Florida, Inc. v. Bevelacqua, 673 So.2d 948 (Fla. Dist. Ct. App. 1993).

Our conclusion is bolstered by the public policy underlying confidentiality laws. Defendants' arguments that disclosure of the study participants will chill future volunteers is a valid point. Additionally, once medical information is disclosed, it can never be retrieved. *See* Limbaugh v. State, 887 So.2d 387, 401 (Fla. Dist. Ct. App. 2004) (May, J., concurring in part and dissenting in part). And while the Federal Rules of Civil Procedure do allow for broad disclosure, Rule 26(b)(1) specifically states that "[p]arties may obtain discovery regarding any matter, not privileged...."[7]

In its current form, the clinical study participant questionnaire is not discoverable without redaction. We do believe, however, that plaintiff is entitled to the discovery of the names of the participants in the study, as long as they are divorced from the medical information unique to each participant. Thus, we hold that defendants must produce the four-page informed consent forms from both studies without redacting the participant's or witness' names. Because we find that it is irrelevant and may lead to further discovery not allowed by this court, participant's clinic number must be redacted. Plaintiff is not entitled to the unredacted copies of the patient eligibility or pain assessment forms, which comprise the remaining pages of the clinical study participant questionnaire. And because plaintiff should not be able to connect the name on an unredacted informed consent form with any medical information, the unique number currently assigned to each questionnaire should be removed

[7]The confidentiality of medical records is a matter of privilege in Florida and Illinois. *See* In re Fink, 876 F.2d at 85 (applying Florida law); Northwestern Mem'l Hosp. v. Ashcroft, 362 F.3d at 925 (applying Illinois law).

from the informed consent forms.[8] If need be, a different identifying number can be assigned. Further, because the study participants were involved in a health care clinical study, and their names should be protected, parties must enter into a qualified protective order similar to the one proposed by plaintiff.

CONCLUSION

For the reasons stated above, we deny in part plaintiff's motion to compel. We hold that plaintiff may access copies of the informed consent form with the names of the participants and witnesses. Participants' clinic numbers will be redacted. Plaintiff's request for the remainder of the unredacted clinical study participant questionnaire is denied.

JAMES B. MORAN
Senior Judge, U. S. District Court

May 15, 2006.

[8]Defendants argue that if the court orders them to produce unredacted patient records, Florida law requires notice to the patients and an opportunity to object. Because we have determined that the informed consent forms are not medical records, F.S.A. § 456.057(6) is inapplicable.